REMARKS

Claims 3-16 and 43 are pending in the instant application. Claim 3 has been amended herein. Claims 1, 2, 17-42, and 44 have been canceled without prejudice.

Claim 3 has been amended to delete the term, "without drug selection", and to specify that the "enriching the cells for GGTA1 null cells" is "by treating the cells with agents that specifically bind an α(1,3)-galactose epitope and that deplete cells that express the epitope." Support for this amendment is found throughout the original specification as filed. See, for example, paragraph [0069] of the specification (published as US 20060242722; emphasis added):

> In contrast, the present invention involves selection of cells with mutations in the functional allele of heterozygous GGTA1 cells or somatic recombination leading to GGTA1 null cells without using a second drug selector such as G418. Repeated **selection against cells expressing GGTA1** is performed by **exposure to affinity purified primate antibodies against the α-1,3-gal epitope** followed by **lysis with complement**. As an alternative or supplement treatment, **depletion of cells expressing GGTA1** is performed by, with or without first treating the cells with **anti-gal reagents**, including but not limited to, gal epitope ligands or anti-galactose-α(1,3)-galactose antibodies, followed by using the appropriately coated magnetic micro-beads. The antibody/complement treatment and the depletion can be repeated multiple times in any order. Use of the above processes results in a population of cells sufficiently enriched in GGTA1 null cells for direct use in nuclear transfer. Alternatively, enriched cell populations may be cloned, with or without additional selection with antibody and complement or depletion as described above. Similar selection may be performed with **other agents which specifically bind the α-1,3-gal epitope and lead to cell death** or permit physical separation of binding and non-binding cell populations.

See also paragraphs [0012], [0013], [0046], and the Examples. No new matter has been added by this amendment.

The following remarks are in response to the office action mailed June 26, 2008 ("the office action"). With this response, Applicant respectfully submits the following remarks and

assert that claims are in condition for allowance and request that the Examiner acknowledge the same.

Information Disclosure Statements

Applicants respectfully request that the Examiner consider the references listed on the PTO-1449 form filed with the Information Disclosure Statement on December 28, 2007, and return an initialed copy. Applicants also request that the Examiner consider the reference listed on the PTO-1449 form filed with the Information Disclosure Statement herewith.

Rejections under 35 U.S.C. § 112, first paragraph (written description)

Claims 3-16 and 43 were rejected as allegedly failing to comply with the written description requirement. According to the office action,

> Claim 3, from which claims 4-16 and 43 depend, has been amended to state 'enriching for GGTA1 null cells without drug selection.' However, there is no evidence in the specification that applicant enriching [sic] without drug selection. The specification does not disclose selection without exposure to a drug. In fact, the specification discloses selection by multiple rounds of antibody selection of Gal positive cells followed by complement mediated lysis. Both the Gal antibodies and complement are drugs in that they are bioeffective. Thus, there is no contemplation of selection without exposure to a drug.

Although Applicants respectfully disagree with the assertion that the specification fails to contemplate selection without exposure to drug and with the Examiner's interpretation of "drug", it is believed that this rejection is met by the present amendment to claim 3. Claim 3 has been amended to delete the term "without drug selection," and to indicate that the enriching for GGTA1 null cells is by treating the cells with agents that specifically bind an α(1,3)-galactose epitope and that deplete cells that express the epitope. The specification clearly contemplates agents that specifically bind an α(1,3)-galactose epitope. See, e.g., paragraphs [0013] and [0069] which refers to anti-gal reagents, including gal epitope ligands, lectin, and anti-galactose-α(1,3)-galactose antibodies. The specification also contemplates agents that deplete cells that express

an α(1,3)-galactose epitope, such as magnetic beads bound to an anti-antibody and complement. Moreover, methods of enriching for cells as set forth in the claims are exemplified in the specification (see the Examples). Accordingly, there is more than sufficient written description for claim 3 and for claims 4-16 and 43, which depend from claim 3.

The office action also stated that "Applicant must cancel the new matter added to claim 3 or provide evidence of contemplation." Although Applicants disagree that the term "without drug selection" constituted new matter, it is noted that this term has been canceled from the claim.

In view of the foregoing, withdrawal of the rejection of claims 3-16 and 43 as lacking written description is respectfully requested.

Rejections under 35 U.S.C. § 112, first paragraph (enablement)

Claims 3-16 and 43 were rejected as allegedly failing to comply with the enablement requirement. The office action states:

> The specification does not provide any guidance or teachings on a methodology that would permit selection of null, homozygous knockout, GGTA1 cells. The specific disclosure is to expose the GGTA1 cells to multiple rounds of Gal-antibody and complement to lysis [sic] cells that bind the antibody. However, as antibodies and complement are bioeffective compounds, they fall within the category of 'drugs.' Thus, the specification fails to enable the invention as presently claimed.

Applicants believe that this rejection is overcome by the amendment to claim 3 to delete the term "without drug selection," and to indicate that the enriching for GGTA1 null cells is by treating the cells with agents that specifically bind an α(1,3)-galactose epitope and that deplete cells that express the epitope. Claim 3, as amended, refers to subject matter indicated as enabled in the office action, namely, use of agents that bind α(1,3)-galactose epitopes and that deplete cells that express the epitopes. Accordingly, withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the amendments and the arguments above, Applicant submits that all rejections have been overcome and claims 3-16 and 43 are in condition for allowance. The Examiner is invited to telephone the undersigned attorney to discuss any remaining issues. Early and favorable action is respectfully solicited.

This response is being filed electronically with a petition for extension of time and required fees. It is believed no additional fees are due in connection with this submission. However, in the event any additional fees or extensions are due, please consider this a petition therefore, and please charge any fees associated with this filing, or apply any credits, to Deposit Account No. 03-1721, referencing attorney docket no. 0492479-0316.

Respectfully submitted,

Choate, Hall & Stewart, LLP

Dated: November 26, 2008

/Margo H. Furman/
Margo H. Furman, Ph.D.
Registration No.: 59,812
Attorney for Applicant

Choate, Hall & Stewart, LLP
Two International Place
Boston, Massachusetts 02110
(617) 248-5000
(617) 502-5002 (Fax)
patentdocket@choate.com